# **Exhibit P**

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# 2021, Apr. 2021 Release CP:Procedures

Subset: 6,7 Gender Affirmation Surgery

**Requested Service:** Hysterectomy for Gender Affirmation Surgery

**Age:** Age  $\geq 18$ 

Patient:	Name:	DOB:	ID #:	GROUP #:
	Sex (circle): M / F	Height:	Weight:	
Provider/PCP:	Name:	Fax #:	Phone #:	
	NPI/ID #:	Signature:		Date:
Servicing:	Vendor/Facility:		Phone #:	
	Diagnosis/ICD:	Service Date:	Authorizat	ion:

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CPT®:

### **INSTRUCTIONS:** Answer the following questions

### □ 10. Primary gender affirmation surgery

- $\mathfrak{P}$ ? Strong and persistent cross-gender identification  $\geq 6$  months
  - □ A) Yes
  - □ B) No
    - If option Yes selected, then go to question 2
    - No other options lead to the requested service

# 2. Choose all that apply:

- □ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
- □ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
- □ C) Strong desire to have primary or secondary sex characteristics of the other gender
- □ D) Strong desire to be the other gender or an alternative gender
- □ E) Strong desire to be treated as the other gender
- □ F) Strong confidence that typical feelings and reactions are of the other gender
- □ G) Other clinical information (add comment)
  - If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
  - No other options lead to the requested service

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Gender Affirmation Surgery

Hysterectomy for Gender Affirmation Surgery

# *Primary gender affirmation surgery (continued...)*

9. Choose all that apply	(3)	Choose	all	that	app	lν
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- □ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
- □ B) Clinically significant increased risk of suffering
- □ C) Other clinical information (add comment)
  - If 1 or more options A or B selected and option C not selected, then go to question 4
  - No other options lead to the requested service

# 4. Gender affirmation surgery, Choose one:

- □ A) Female-to-male surgery, genital
- □ **B**) Female-to-male surgery, other
- □ C} Male-to-female surgery, genital
- □ 🗗 Male-to-female surgery, other
- □ E) Other clinical information (add comment)
  - If option A selected, then go to question 5
  - No other options lead to the requested service

# 5. Choose all that apply:

- □ A Referrals from two behavioral health specialists clearing patient for gender affirmation surgery
- □ **B**)Persistent and well-documented gender dysphoria
- □ (¹¾)Capacity to make fully informed decisions and to consent
- □ 🗗 No psychiatric disorder by history or psychiatric disorder controlled
- □ E) Other clinical information (add comment)
  - If the number of options selected is 4 and option E not selected, then go to question 6
  - No other options lead to the requested service

### 6. Choose all that apply:

- $\square$  (A) Cross-sex hormone therapy  $\ge 12$  months or hormone therapy contraindicated
- $\square$  B) Lived  $\ge 12$  months in gender role congruent with gender identity
- □ C) Other clinical information (add comment)
  - If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here
  - No other options lead to the requested service

### Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

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Gender Affirmation Surgery

Hysterectomy for Gender Affirmation Surgery

# Notes:

1:

InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:

Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:

Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

**4:** 

According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).

Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013). GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-tofemale and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Case 3:20-cv-00740 Document 254-17 Filed 05/31/22 Page 5 of 17 PageID #: 7770 2021, Apr. 2021 Release CP:Procedures

Gender Affirmation Surgery

Hysterectomy for Gender Affirmation Surgery

Association for Transgender Health. 2011, 7: 1-112).

### 5:

Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

### 6:

These criteria include the following procedures:

Bilateral Mastectomy **Breast Augmentation** Clitoroplasty **Gender Confirmation Surgery** Gender Reassignment Surgery Hysterectomy **Intersex Surgery** Labiaplasty Male Chest Contouring Metoidioplasty Orchiectomy Ovariectomy Penectomy Penile Prosthesis Permanent Hair Removal **Phalloplasty** Salpingo-oophorectomy Scrotoplasty Sex Reassignment Surgery **Transgender Surgery** Transsexual Surgery Urethroplasty Vaginoplasty Vulvoplasty

### 7:

InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

# 8:

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Gender Affirmation Surgery

Hysterectomy for Gender Affirmation Surgery

This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

#### 9:

Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

### 10:

The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingooophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 11:

Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 12:

The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

# **13:**

Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 14:

Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

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**Hysterectomy for Gender Affirmation Surgery** 

Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 15:

It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 16:

A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 17:

Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

### 18:

Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

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Gender Affirmation Surgery

Hysterectomy for Gender Affirmation Surgery

A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

### 19:

Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 20:

I/O Setting:

Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. setting.

Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. All others - Outpatient

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InterQual®

Gender Affirmation Surgery

Hysterectomy for Gender Affirmation Surgery

ICD-10-CM (circle all that apply): F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890, Other
ICD-10-PCS (circle all that apply): 0UT90ZL, 0UT90ZZ, 0UT94ZL, 0UT94ZZ, 0UT97ZL, 0UT97ZZ, 0UT98ZL, 0UT9FZL, 0UT9FZZ, 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ, Other
<b>CPT</b> ® <b>(circle all that apply):</b> 58150, 58180, 58260, 58262, 58275, 58290, 58291, 58541, 58542, 58543, 58544, 58552, 58553, 58554, 58570, 58571, 58572, 58573, Other

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# 2021, Apr. 2021 Release CP:Procedures

Subset: 6,7 Gender Affirmation Surgery

**Requested Service:** Phalloplasty for Gender Affirmation Surgery

**Age:** Age  $\geq 18$ 

Name:	DOB:	ID #:	GROUP #:
Sex (circle): M / F	Height:	Weight:	
Name:	Fax #:	Phone #:	
NPI/ID #:	Signature:		Date:
Vendor/Facility:		Phone #:	
Diagnosis/ICD:	Service Date:	Authoriz	ation:
	Sex (circle): M / F  Name:  NPI/ID #:  Vendor/Facility:	Sex (circle): M / F Height:  Name: Fax #:  NPI/ID #: Signature:  Vendor/Facility:	Sex (circle): M / FHeight:Weight:Name:Fax #:Phone #:NPI/ID #:Signature:Vendor/Facility:Phone #:

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CPT®:

### **INSTRUCTIONS:** Answer the following questions

□ 10. Primary gender affirmation surgery

- $\mathfrak{P}$ ? Strong and persistent cross-gender identification  $\geq 6$  months
  - □ A) Yes
  - □ B) No
    - If option Yes selected, then go to question 2
    - No other options lead to the requested service
- 2. Choose all that apply:
  - □ A) Marked incongruence between experienced or expressed gender and primary or secondary sex characteristics
  - □ B) Strong desire to not have current primary or secondary sex characteristics because of the incongruence with experienced or expressed gender
  - □ C) Strong desire to have primary or secondary sex characteristics of the other gender
  - □ D) Strong desire to be the other gender or an alternative gender
  - □ E) Strong desire to be treated as the other gender
  - □ F) Strong confidence that typical feelings and reactions are of the other gender
  - □ G) Other clinical information (add comment)
    - If 2 or more options A, B, C, D, E or F selected and option G not selected, then go to question 3
    - No other options lead to the requested service

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Gender Affirmation Surgery

Phalloplasty for Gender Affirmation Surgery

# Primary gender affirmation surgery (continued...)

	(3)	Choose	all	that	app	lν
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- □ A) Clinically significant distress or impairment in social or occupational or other important areas of functioning
- □ B) Clinically significant increased risk of suffering
- □ C) Other clinical information (add comment)
  - If 1 or more options A or B selected and option C not selected, then go to question 4
  - No other options lead to the requested service

# 4. Gender affirmation surgery, Choose one:

- □ A) Female-to-male surgery, genital
- □ **B** Female-to-male surgery, other
- □ C} Male-to-female surgery, genital
- □ 🗗 Male-to-female surgery, other
- □ E) Other clinical information (add comment)
  - If option A selected, then go to question 5
  - No other options lead to the requested service

# 5. Choose all that apply:

- □ A Referrals from two behavioral health specialists clearing patient for gender affirmation surgery
- □ **B**)Persistent and well-documented gender dysphoria
- □ 🖰 Capacity to make fully informed decisions and to consent
- □ 🗗 No psychiatric disorder by history or psychiatric disorder controlled
- □ E) Other clinical information (add comment)
  - If the number of options selected is 4 and option E not selected, then go to question 6
  - No other options lead to the requested service

### 6. Choose all that apply:

- $\square$  (A) Cross-sex hormone therapy  $\ge 12$  months or hormone therapy contraindicated
- $\square$  B) Lived  $\ge 12$  months in gender role congruent with gender identity
- □ C) Other clinical information (add comment)
  - If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here
  - No other options lead to the requested service

### Reference

Ltd - This requested service is designated as 'Limited Evidence' in this clinical scenario. Criteria cannot be met.

2nd - Secondary review required. Criteria cannot be met.

Off-label - Use of a drug for an indication not approved by the U.S. Food and Drug Administration (FDA).

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Gender Affirmation Surgery

Phalloplasty for Gender Affirmation Surgery

# Notes:

1:

InterQual® content contains numerous references to gender. Depending on the context, these references may refer to either genotypic or phenotypic gender. At the individual patient level, a variety of factors, including, but not limited to, gender identity and gender affirmation via surgery or hormonal manipulation, may affect the applicability of some InterQual criteria. This is most often the case with genetic testing and procedures that assume the presence of gender-specific anatomy. With these considerations in mind, all references to gender in InterQual have been reviewed and modified when appropriate. InterQual users should carefully consider issues related to patient genotype and anatomy, especially for transgender individuals, when appropriate.

2:

Delaying treatment for those with gender dysphoria is not a reasonable treatment option. This can lead to negative consequences, such as delay or arrest in emotional, social, or intellectual development. Isolating oneself from family and friends, being excluded from society, becoming a victim of bullying and self-harm all may be seen when there is an impediment or interruption in care. Some individuals, notably adolescents, may develop psychiatric issues including anxiety, depression, and suicidal ideation (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

3:

Guidelines agree that gender affirmation surgical intervention is appropriate for individuals 18 years of age or older, as these procedures are irreversible; however, behavioral health counseling and hormone therapy may be used to treat individuals who have been diagnosed with gender dysphoria at an earlier age. The sooner the diagnosis is made and treatment options are discussed, the more successful the individual is when transitioning (Hembree et al., Endocr Pract 2017, 23: 1437; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

4:

According to the American Psychiatric Association, the Diagnostic and Statistical Manual of Mental Disorders defines gender dysphoria as a condition where sex assigned at birth is incongruent with experienced or desired gender, resulting in distress and suffering. Distress must persist for at least six months and result in a desire to change (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). Transgender persons are described as someone whose gender identity, behavior or expression, is not typical of that assigned at birth, including those who are gender dysphoric. In the United States, approximately 0.6%, or 1.4 million adults identify as transgender individuals. The prevalence is similar worldwide and has doubled in the last decade (Flores et al., How many adults identify as Transgender in the United States? 2016).

Therapeutic options for gender dysphoria or transgender individuals include psychotherapy, hormonal treatment, and gender affirmation surgery (GAS). Dressing, acting, or speaking consistent with the correct gender, taking hormones, changing one's name, and surgical intervention are possible activities carried out to identify with the correct gender. Some transgender individuals do not define themselves as conforming to the gender binary (male or female) and may also use terms such as gender non-conforming, pangender, agender, bigender, polygender, gender fluid, gender queer, or gender neutral. This will impact their treatment choices (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013). GAS is a treatment option for gender dysphoria and is often the final stage of transition. GAS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities working in conjunction with each other to assist the candidate for gender affirmation achieve successful outcomes. Before undertaking GAS, candidates need to undergo important medical and psychological evaluations to confirm that surgery is the most appropriate treatment choice. Procedures vary significantly from female-to-male and male-tofemale and are generally comprised of a series of primary and secondary sex character changes, chest reconstruction, facial alterations and voice-modification. After working with a transgender care team, a surgical plan is tailored to the individual's needs to relieve gender dysphoria. Treatment standardization in this population is not possible as clinical presentations and symptoms will vary significantly with each individual. A specialized, multidisciplinary transgender care team may include, but is not limited to, practitioners in primary care, behavioral health, speech and language therapy, dermatology, endocrinology, urology, gynecology, and plastic surgery. Collaborative care, joint participation in goal setting along with regular follow-up is crucial (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Case 3:20-cv-00740 Document 254-17 Filed 05/31/22 Page 13 of 17 PageID #: 7778 2021, Apr. 2021 Release CP:Procedures

Gender Affirmation Surgery

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Association for Transgender Health. 2011, 7: 1-112).

### 5:

Although there are many publications on gender affirmation surgery (GAS), most articles are observational case studies, have less than 30 participants, do not have strong evidence, or are focused on surgical technique. There is a paucity of published evidence that is adequately powered or designed to allow definitive conclusions on safety and efficacy of the individual surgical procedures. Surgical technique and observational case studies represent the largest body of evidence. Future research is needed to improve patient selection, surgical procedure selection and patient outcome.

Statistics around GAS are primarily estimations. Private facilities are not mandated to report this data; there are variations on how surgical procedures are staged and many of the procedures are identified as simply cosmetic, therefore making data collection difficult. In addition, the complexity and various reconstructive scenarios distinguishing procedures with multiple stages from revisional affirmation surgery is not truly accounted for. Although estimates vary, the American Society of Plastic Surgeons stated that there was a 155% increase in gender affirmation surgeries in 2017, approximating over 8,300 facial, body contouring and sex surgeries (American Society of Plastic Surgeons, 2017 Plastic Surgery Statistics Report. 2018).

### 6:

These criteria include the following procedures:

Bilateral Mastectomy **Breast Augmentation** Clitoroplasty **Gender Confirmation Surgery** Gender Reassignment Surgery Hysterectomy **Intersex Surgery** Labiaplasty Male Chest Contouring Metoidioplasty Orchiectomy Ovariectomy Penectomy Penile Prosthesis Permanent Hair Removal **Phalloplasty** Salpingo-oophorectomy Scrotoplasty Sex Reassignment Surgery **Transgender Surgery** Transsexual Surgery Urethroplasty Vaginoplasty Vulvoplasty

### 7:

InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, ECRI Guidelines Trust®, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

# 8:

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This is a procedure that can be performed for either medically necessary or cosmetic purposes. The criteria as written are intended solely for use in determining the medical appropriateness of this procedure and do not cover this procedure when performed for cosmetic reasons.

#### 9:

Prior to surgical intervention for gender affirmation, gender dysphoria must be present as outlined by the Diagnostic and Statistical Manual of Mental Disorders. If a pronounced distress between the assigned gender at birth and the gender that is desired persists for at least six months, and there is significant distress in social or occupational settings, the diagnosis of gender dysphoria can be made. It is accompanied by marked incongruence between experienced or expressed gender and sex characteristics, strong desire to be an alternate gender, strong desire to be treated as the other gender, to not have or to change assigned sex characteristics, or having strong confidence that typical feelings are of the other gender (American Psychiatric Association, The Diagnostic and Statistical Manual of Mental Disorders: DSM-5. 2013). InterQual® consultants agree that the Diagnostic and Statistical Manual of Mental Disorders is the most widely accepted for the diagnosis of gender dysphoria.

### 10:

The most common female-to-male (FtM) genital procedures include hysterectomy, ovariectomy, salpingooophorectomy, metoidioplasty, phalloplasty, penile prosthesis, scrotoplasty, and urethroplasty. Permanent hair removal can be done prior to a number of genital surgeries.

The most common FtM chest procedures are mastectomy and male chest contouring. There are also various body contouring, facial and voice modification surgeries (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 11:

Surgical risks in female-to-male (FtM) genital and breast surgeries include, but are not limited to, infection, unsightly scarring, nipple necrosis, contour irregularities, urinary tract stenosis, fistulas, necrosis of neophallus, micropenis, and incapacity to stand while urinating. FtM genital surgery has been less successful than male-to-female genital surgery because of the difficulty creating a functional and aesthetic penis from smaller clitoral tissue (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 12:

The most common male-to-female (MtF) genital procedures include orchiectomy, penectomy, clitoroplasty, labiaplasty, urethroplasty, vaginoplasty, and vulvoplasty.

The most common MtF chest procedure is breast augmentation. Permanent hair removal can be done prior to a number of genital surgeries. There are also various body contouring, facial and voice modification surgeries that may be appropriate MtF procedures (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

# **13:**

Some surgical risks in male-to-female genital and breast augmentation surgeries include, but are not limited to, infection, capsular fibrosis, partial necrosis of the vagina or labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, the vagina being too short or small for coitus, anorgasmia, lower urinary tract infection from a shortened urethra, and dysfunctional bladder (Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 14:

Therapy is intended to explore gender concerns, assess the intensity of and help alleviate gender dysphoria, assist in determining appropriate subsequent steps in treatment, assess existing mental health concerns, and evaluate outcomes of interventions (Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). A behavioral health specialist must document persistent gender dysphoria, the ability to make fully informed decisions, and assure there are no active psychiatric disorders to impede decision making or interfere with successful postoperative care (Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). The individual should be assessed before surgery and demonstrate an understanding of the procedure, surgical options, and potential risks and outcomes. The patient should be aware of the risk of sterility as a result of hormone therapy and gender affirmation surgery. Discussions regarding fertility preservation options prior to these interventions, as well as ongoing oncological risk monitoring, are necessary (Hembree et al., Endocr

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Pract 2017, 23: 1437; Wylie et al., Lancet 2016, 388: 401-11; American Psychological, Am Psychol 2015, 70: 832-64; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112). There is no recommended length of therapy or number of sessions an individual must attend or complete preceding surgery. It is however, strongly suggested that transgender individuals have access to therapy throughout the process as it can be a supportive adjunct to gender affirming surgery (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 15:

It is required that individuals seeking chest or breast surgery, to treat gender dysphoria, submit one referral letter from a behavioral health specialist to the surgeon stating psychotherapy requisites have been met. Surgeons generally require two referral letters before proceeding with genital surgery. It is recommended that at least one of the behavioral health professionals submitting a letter should have a doctoral degree (e.g., Ph.D., M.D., Ed.D., D.Sc., D.S.W., Psy.D) or a master's level degree in a clinical behavioral science field (e.g., M.S.W., L.C.S.W., Nurse Practitioner, Advanced Practice Nurse, Licensed Professional Councilor, Marriage and Family Therapist). Since there is not a standardized letter format outlining specific content that needs to be communicated between the behavioral health specialist and surgeon, letter writing varies. Often, referrals will include diagnostic criteria of gender dysphoria from the Diagnostic and Statistical Manual of Mental Disorders, standards of care met from The World Professional Association for Transgender Health, the individual's duration and compliance with therapy, as well as an understanding of procedures, individual readiness and consent. Typically, an explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the individual's request for surgery are also recorded. Ideally, the mental health professional should document willingness to coordinate care with the primary and surgical care team (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 16:

A significant number of gender dysphoric patients have a history of diagnosed or undiagnosed psychopathology including substance abuse, post-traumatic stress disorder, mood disorders, and anxiety. Although no specific conditions are exclusionary, all patients should be screened to ensure stability and a complete understanding of the procedure and postoperative follow-up. Depression may occur anytime throughout the transition process and individuals are encouraged to continue with psychotherapy during and after transition as needed (Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Dhejne et al., Int Rev Psychiatry 2016, 28: 44-57; Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

### 17:

Symptoms or behaviors are considered to be controlled when they have responded to therapeutic and/or pharmacologic interventions.

### 18:

Surgical intervention should not be performed until the patient is 18 years or older. Hormone therapy, however, may begin sooner if not contraindicated. Guidelines suggest pubertal suppression can begin at Tanner stage 2 as better outcomes are seen when initiated with puberty. These guidelines do not agree on an age to begin cross-sex hormone therapy, but do agree that cross-sex hormone therapy should be taken for at least 12 months prior to genital surgery and female-to-male (FtM) mastectomy, and male chest contouring. For best results in male-to-female (MtF) breast augmentation surgery, some guidelines suggest at least 2 years of cross-sex hormone therapy because breasts continue to grow during this time, while others agree 12 months is sufficient (Hembree et al., Endocr Pract 2017, 23: 1437; Deutsch M. B., Center of Excellence for Transgender Health 2016, 2 ed; Fisher et al., J Endocrinol Invest 2014, 37: 675-87; Moreno-Perez and Esteva De Antonio, Endocrinologia y Nutricion 2012, 6: 367-82; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112; Hembree, Child Adolesc Psychiatr Clin N Am 2011, 20: 725-32).

Pubertal suppressing hormones halt gonadotropin secretion and lead to gradual regression of development of sex characteristics. Girls breasts will not continue to grow and will reduce in size, and menstruation will stop. Boys will experience a cessation in virilization and decreased testicular volume. The effects of these hormones are fully reversible. If the patient has surpassed puberty, cross-sex hormone therapy can begin. Cross-sex hormone therapy leads to the development of opposing sex characteristics and is only partially reversible. In FtM patients, the aim of cross-sex hormone therapy is to cause gradual clitoral enlargement, vaginal atrophy, fat redistribution, voice deepening, facial and body hair growth, suppress menses as well as increase libido, muscle mass and height. The goal for MtF individuals is to reduce height, decrease libido, grow breasts, redistribute body fat, decrease muscle mass, and soften the skin (Hembree et al., Endocr Pract 2017, 23: 1437).

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A systematic review reports that hormonal treatment improves depression, self-esteem, anxiety, personality-related psychopathology, and higher emotional quality of life in both FtM and MtF patients. This review also suggests improved body uneasiness in MtF. Many individuals do not continue with affirmation surgery if hormone therapy and other lifestyle changes have significantly decreased gender dysphoria (Costa and Colizzi, Neuropsychiatr Dis Treat 2016, 12: 1953-66).

### 19:

Living in the preferred gender role congruent with gender identity is a key component to successful transition prior to irreversible genital intervention. A minimum of twelve months is required to experience life events and incorporate transition in different personal and social settings. External response is observed and allows the individual to experience everyday life as the gender they identify with. Continuous living in the correct gender role must be documented by a behavioral health specialist (Royal College of Psychiatrists, Good practice guidelines for the assessment and treatment of adults with gender dysphoria. 2013; Coleman, The World Professional Association for Transgender Health. 2011, 7: 1-112).

# 20:

I/O Setting:

Bilateral Mastectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Clitoroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Hysterectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Intersex Surgery - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. setting.

Metoidioplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Ovariectomy/Salpingo-oophorectomy - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting.

Phalloplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Scrotoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Urethroplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. Vaginoplasty - Due to variations in practice, this procedure can be performed in the inpatient or outpatient setting. All others - Outpatient

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CPT® (circle all that apply): 55899, Other	